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Munich, 8th July 2004

Our ref: 99 625 r15/r4/lcl International Application PCT/EP 03/008067 Sherwood Services AG et al.

In response to the written opinion dated 8th April, 2004, we file herewith new claims 1 to 24 and replacement description pages 1, 2, 2a, 4, 16, 18, 19 and 19a to replace, without prejudice, claims 1 to 27 and description pages 1, 2, 4, 16, 18 and 19 presently on file.

A manuscript-amended version of the claims and description pages is enclosed, to assist in following our changes.

CLAIMS

In the new claims, independent claim 1 has been amended to include the features of original claims 4 and 5. New claim 1 now defines that the arcuate section firstly curves away from the longitudinal axis in a first direction and then curves back towards the longitudinal axis in a second direction, with each curve having its own radius of curvature.

Original claims 6 to 26 have been re-numbered, and the dependencies changed where appropriate, to conform with new claim 1. Minor amendments have been effected to new dependent

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claims 5, 6 and 14 (original claims 7, 8 and 16) for reasons of clarity and consistency.

Original claim 27 has been excised.

Reference signs in parentheses have been inserted into the claims throughout.

DESCRIPTION PAGES

The description has been amended in order to bring it into conformity with the new claims. References to non-published applications and incorporations by reference have been removed from the application throughout. The full extent of our changes will be apparent from the enclosed hand-written working pages.

Roy Marsh

European Patent Attorney

Association No. 151

Encl. New claims 1 to 24; 1-fold

Manuscript-amended claims; 1-fold

Replacement description pages 1, 2, 2a, 4, 16, 18, 19 and 19a; 1-fold

Manuscript-amended description pages; 1-fold

Int. Application No. PCT/EP 03/008067 Sherwood Services AG et al.

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CLAIMS:

- 1. A surgical instrument (10) for passing a material into a body in a minimally invasive procedure comprising:
- a first member (12) having a longitudinal section (16) defining a longitudinal axis and an arcuate section (18) extending distally from the longitudinal section, wherein:
- a proximal portion (36) of the arcuate section curves away from the longitudinal axis in a first direction and defines a first radius of curvature (R1); and
- a portion (38, 40) of the arcuate section distal of the proximal portion (36) curves toward the longitudinal axis in a second direction and defines a second radius of curvature (R2, R3).
- 2. The surgical instrument as recited in claim 1, wherein the first member comprises a hollow outer tubular member.
- 3. The surgical instrument as recited in claim 2, further comprising a stylet (14) at least partially movable within the outer tubular member and engageable with a material to pass the material within the body.
- 4. The surgical instrument as recited in claim 1, wherein a distal portion (40) of the arcuate section has a third radius of curvature

- (R3), different from the second radius of curvature (R2).
- 5. The surgical instrument as recited in claim 4, wherein the portion of the arcuate section distal of the proximal portion (36) has a central section (38) and a distalmost section (40), the central section having the second radius (R2) and the distalmost section having the third radius (R3), the second radius (R2) being larger than the third radius (R3).
- 6. The surgical instrument as recited in claim 4, wherein the portion of the arcuate section distal of the proximal portion (36) has a central section (38) and a distalmost section (40), the central section having the second radius (R2) and the distalmost section having the third radius (R3), the second radius (R2) being smaller than the third radius (R3).
- 7. The surgical instrument as recited in claim 1, wherein a portion of the distal section extends across the longitudinal axis in the second direction.
- 8. The surgical instrument as recited in claim 3, wherein the stylet (14) is flexible.
- 9. The surgical instrument as recited in claim 3, wherein the stylet (14) includes a slot (28) at a first end (26) for receipt of an end of a

material.

- 10. The surgical instrument as recited in claim 3, wherein the stylet (14) includes a conical tip (24) at a second end.
- 11. The surgical instrument as recited in claim 10, wherein a diameter (d3) of the conical tip (24) is greater than an inner diameter of the outer tubular member.
- 12. The surgical instrument as recited in claim 2, wherein the outer tubular member (12) has a handle (20) at a proximal end (22) thereof.
- 13. The surgical instrument as recited in claim 12, wherein the handle has a laterally extending portion (44).
- 14. The surgical instrument as recited in claim 13, wherein the arcuate section (18) defines a first plane and the laterally extending portion defines a second plane substantially perpendicular to the first plane.
- 15. The surgical instrument as recited in claim 3, further comprising a material and wherein the material comprises a generally flat tape (50).
- 16. The surgical instrument as recited in claim 15, wherein at least one end (54) of the tape (50) is cut at an angle for ease of threading the tape

into the stylet.

- 17. The surgical instrument of claim 15, wherein the tape (50) comprises a material including multifilament strands.
- 18. The surgical instrument of claim 17, wherein the tape (50) comprises polypropylene strands.
- 19. The surgical instrument of claim 3, wherein the material comprises a generally flat tape (50) and the stylet (14) has a proximal end (26) adapted to receive an end (54) of the tape.
- 20. The surgical instrument of claim 18, wherein the stylet is positioned in the tubular member (12) so that the proximal end (26) of the stylet is located adjacent a proximal end (22) of the tubular member.
- 21. The surgical instrument of claim 3, wherein the stylet (14) has a distal end that is blunt.
- 22. The surgical instrument of claim 20, wherein the distal end comprises a blunt conical tip (24).
- 23. The surgical instrument of claim 3, wherein the stylet has a distal end that is sharp.
- 24. The surgical instrument of claim 1, further comprising the material and wherein the material comprises an absorbable material.

Int.Application No. PCT/EP03/008067 Sherwood Services AG et al. 99 625 r15/r4/lcl 8.7.04

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IVS OBTURATOR INSTRUMENT AND PROCEDURE

BACKGROUND

1. Technical Field

The technical field relates to insertion instrumentation for inserting material into the body and, more particularly, to an insertion tool and method for inserting a support structure or material into the body to provide a support to the urethra.

2. Background of Related Art

One problem occurring in women due to the onset of advanced age or trauma is urinary stress incontinence. Several therapies have been developed to correct or alleviate this condition, such as, for example drug therapies and surgical procedures. In some cases it is necessary to implant a temporary or permanent structure to support the midline of the urethra to control discharge.

Several surgical procedures have been developed to position a support against the urethra. Many of these procedures require the use and installation of bone anchors to affix the ends of the support to the pubic bone. These procedures are fairly invasive and require complex instruments to install the bone anchors in the pubic bone.

One exemplary device and method of inserting, in a minimally invasive manner, a sling support within the body to support the urethra is disclosed in certain embodiments of U.S. Patent No. 5,112,344 to Petros. The Petros

reference discloses the use of an instrument to insert a length of tape through incisions in the abdomen and the vagina so that the tape supports the urethra. No bone anchors or other auxiliary structures are used to anchor the tape. While inserting the tape into the body using the instrument, the instrument passes through the patient's body on either side of the bladder. Although this instrument is designed to safely pass from the incision in the vagina to the incision in the abdomen, surgeons typically perform a cystoscopy to check the integrity of the bladder.

It is desirable to have other methods of inserting, in a minimally invasive manner, support structure or material into the body without having to pass an instrument through the body on either side of the bladder.

SUMMARY

According to the present invention, there is provided a surgical instrument for passing a material into a body in a minimally invasive procedure comprising:

a first member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section, wherein:

a proximal portion of the arcuate section curves away from the longitudinal axis in a first direction and defines a first radius of curvature; and

a portion of the arcuate section distal of the proximal portion curves toward the longitudinal axis in a second direction and defines a second radius of curvature. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive

procedure.

The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

In certain preferred embodiments, the first member comprises a hollow outer tubular member. A stylet is at least partially movable within the outer tubular member and engageable with a material to pass the material within the body. The hollow outer tubular member and stylet enable the surgeon to remove the stylet from the outer tubular member and reinsert the stylet in the opposite position with respect to the outer tubular member. This structure also facilitates the placement of the material so that the material extends from a first side of the pelvis to a second side of the pelvis.

A proximal portion of the arcuate section curves away from the longitudinal axis in a first direction _____

distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

In the present invention, the surgical instrument for passing a material into a body in a minimally invasive procedure may have the arcuate section dimensioned and curved whereby when in use and in position in the body, the arcuate section extends from the skin over the obturator foramen, through the obturator foramen, to the vaginal wall. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings wherein:

FIG. 1 is a side view of an instrument for use in a surgical procedure in accordance with an embodiment of the present invention;

FIG. 2 is a side view of an outer member of the instrument in accordance with the embodiment of FIG. 1; FIG. 3

is a bottom view of the outer member of the instrument in accordance with the embodiment of FIGS. 1 and 2;

FIG. 4 is a side view of a stylet of the instrument in accordance with the embodiment of FIGS. 1-3;

FIG. 5 is a perspective view of a length of material used with the instrument in accordance with the embodiment of FIGS. 1-4;

FIG. 6 is a sketch showing the relation of the vagina to the pelvis;

FIG. 7 is a black and white photograph of the vaginal area during an initial stage of a surgical procedure in accordance with a further embodiment of the invention;

The outer tubular member desirably has a handle at a proximal end thereof. In certain preferred embodiments, the handle has a laterally extending portion. The arcuate section defines a first plane and the wing defines a second plane substantially perpendicular to the first plane.

The surgical instrument preferably includes a material and, in certain preferred embodiments, wherein the material comprises a generally flat tape. At least one end of the tape may be cut at an angle for ease of threading the tape into the stylet, in embodiments in which the stylet comprises a slot for receipt of the at least one end. The tape desirably comprises a material including multifilament strands, which may comprise polypropylene strands. The material may comprise a generally flat tape and the stylet may have a proximal end adapted to receive an end of the tape. The material may comprise an absorbable material.

The stylet is desirably positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member. In certain preferred embodiments, the stylet has a distal end that is blunt. The distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

The arcuate portion has a proximal portion which curves away from the longitudinal axis in a first direction and a distal portion which curves toward the longitudinal axis in a second direction. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

A stylet is at least partially movable within the outer tubular member and engageable with a material to pass the material within the body. The hollow outer tubular comprises a slot for receipt of the at least one end. The tape desirably comprises a material including multifilament strands, which may comprise polypropylene strands. The material may comprise a generally flat tape and the stylet may have a proximal end adapted to receive an end of the tape. The material may comprise an absorbable material.

The stylet is desirably positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member. In certain preferred embodiments, the stylet has a distal end that is blunt. The distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

One method of suspending a portion of the urethra with a length of material comprises the steps of providing a surgical instrument having an outer tubular member including a longitudinal proximal end and a curved distal end and a stylet movable within the tubular member and configured to hold an end of the length of material. The method includes positioning the stylet within the tubular member. A vaginal incision and an incision located over the obturator foramen are made. The curved distal end of the surgical instrument is passed through the incision over the obturator foramen. The method includes manipulating the surgical instrument such that the curved distal end passes through the obturator foramen and out the vaginal incision. A proximal end of the stylet is engaged with a first end of the length of material, and the stylet is drawn through the tubular member to draw a portion of the length of material from the incision over the obturator foramen and through the vaginal incision.

The outer tubular member may be withdrawn through

the incision over the obturator foramen leaving the length of material extending through the obturator foramen and out the vaginal incision. The step of passing the curved distal end of the surgical instrument through the incision over the obturator foramen desirably includes rotating the surgical instrument approximately 30 degrees upward in relation to the body. The surgical instrument is desirably elevated to position the curved distal end through the obturator foramen. The surgical instrument is rotated to pass the curved distal end through the obturator foramen and out the vaginal incision.

Another method of suspending a portion of the urethra comprises the steps of passing a curved distal end of a surgical instrument through the body so that the instrument extends between a vaginal incision and a skin incision located over the obturator foramen. The surgical instrument has an outer tubular member including a longitudinal proximal end and a curved distal end and a stylet movable within the outer tubular member. The stylet is drawn through the body to draw the length of material through the body, extending between the vaginal incision and the incision over the obturator foramen.

The step of passing the curved distal end of the instrument desirably includes inserting the curved distal end of the instrument into the incision over the obturator foramen and moving the curved distal end through the obturator foramen, out the vaginal incision. The step of passing the curved distal end of the instrument desirably includes inserting the curved distal end into the vaginal incision. During the step of passing the curved distal end of the instrument, the stylet is desirably disposed within the outer tubular member.

The method may include, after the step of passing, withdrawing the stylet from the outer tubular member. The stylet may be reinserted in the outer tubular member so that an end of the stylet adapted to receive the material is disposed at the vaginal incision. The material is desirably disposed so that the material is received by the end of the stylet.

The step of drawing may include withdrawing the stylet through the outer tubular member, thereby drawing the material through the outer tubular member, and removing the outer tubular member through the body. The step of drawing may include withdrawing the stylet and outer tubular member from the body, thereby drawing the material through the body.

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CLAIMS

(10)

- 1. A surgical instrument for passing a material into a body in a minimally invasive procedure comprising:
- a first member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section, the arcuate section having at least two different radii of curvature.
- The surgical instrument as recited in claim 1, wherein the first member comprises a hollow outer tubular member.

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- 3. The surgical instrument as recited in claim 2, ((4)) further comprising a stylet at least partially movable within the outer tubular member and engageable with a material to pass the material within the body.
- wherein a proximal portion of the arcuate section curves away from the longitudinal axis in a first direction and defines a first radius of curvature;
- wherein a faistal portion of the arcuate section curves toward the longitudinal axis in a second direction and defines a second radius of curvature.
- 4%. The surgical instrument as recited in claim \$\frac{1}{6}\$, wherein the distal portion of the arcuate section has a third radius of curvature, different from the second radius of curvature.
- wherein the distal portion has a central section having the second (23) radius and the distalmost section having the third radius, the second radius being larger than the third radius.

of the armote section distal of the proximal portion (36)

- wherein the distalmost section having the second radius and the distalmost section section having the third radius, the second radius being smaller than the third radius,
- 7%. The surgical instrument as recited in claim #, wherein a portion of the distal section extends across the longitudinal axis in the second direction.
- %)%. The surgical instrument as recited in claim 3, wherein the stylet is flexible.

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- (26) wherein the stylet includes a slot at a first end for receipt of an end of a material.
- /022. The surgical instrument as recited in claim 3, wherein the stylet includes a conical tiplat a second end.
- Wherein a diameter of the outer tubular member.
- wherein the outer tubular member has a handle at a proximal end thereof.
- 13.78. The surgical instrument as recited in claim M_{\star}^{17} , wherein the handle has a laterally extending portion.
- wherein the arcuate section defines a first plane and the wifig defines a second plane substantially perpendicular to the first plane.
 - 15 \bowtie . The surgical instrument as recited in claim 3, further comprising a material and wherein the material comprises a generally flat tape.

- The surgical instrument as recited in claim \$2, wherein at least one end of the tape is cut at an angle for ease of threading the tape into the stylet.
- 17 bg. The surgical instrument of claim 17, wherein the tape comprises a material including multifilament strands.
- 18 28. The surgical instrument of claim \$9, wherein the tape comprises polypropylene strands.
- The surgical instrument of claim 3, wherein the material comprises a generally flat tape and the stylet has a proximal endiadapted to receive an endiof the tape.
- 20 22. The surgical instrument of claim 20, wherein the stylet is positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member.
- The surgical instrument of claim 3, wherein the stylet has a distal end that is blunt.
- 22. The surgical instrument of claim 22, wherein the distal end comprises a blunt conical tip.
- 2328. The surgical instrument of claim 3, wherein the stylet has a distal end that is sharp.
- 2426. The surgical instrument of claim 1, further comprising the material and wherein the material comprises an absorbable material.

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the arcuate section extends from the skin over the obturator foramen, through the obturator foramen, to the vaginal wall.

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(1,2,4,16,18,19)

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IVS OBTURATOR INSTRUMENT AND PROCEDURE

CROSS REFERENCE TO RELATED APPLICATIONS

The present disclosure claims priority to U.S.

Provisional Application Serial No. 60/397,905, filed July 23,

2002 and entitled IVS OFTURATOR.

BACKGROUND

1. Technical Field

The technical field relates to insertion instrumentation for inserting material into the body and, more particularly, to an insertion tool and method for inserting a support structure or material into the body to provide a support to the urethra.

2. Background of Related Art

One problem occurring in women due to the onset of advanced age or trauma is urinary stress incontinence. Several therapies have been developed to correct or alleviate this condition, such as, for example drug therapies and surgical procedures. In some cases it is necessary to implant a temporary or permanent structure to support the midline of the urethra to control discharge.

Several surgical procedures have been developed to position a support against the urethra. Many of these procedures require the use and installation of bone anchors to affix the ends of the support to the pubic bone. These procedures are fairly invasive and require complex instruments to install the bone anchors in the pubic bone.

One exemplary device and method of inserting, in a minimally invasive manner, a sling support within the body to support the urethra is disclosed in certain embodiments of U.S. Patent No. 5,112,344 to Petros, the entire disclosure of which is hereby incorporated by reference herein. The Petros reference discloses the use of an instrument to insert a length of tape through incisions in the abdomen and the vagina so that the tape supports the urethra. No bone

anchors or other auxiliary structures are used to anchor the tape. While inserting the tape into the body using the instrument, the instrument passes through the patient's body on either side of the bladder. Although this instrument is designed to safely pass from the incision in the vagina to the incision in the abdomen, surgeons typically perform a cystoscopy to check the integrity of the bladder.

It is desirable to have other methods of inserting, in a minimally invasive manner, support structure or material into the body without having to pass an instrument through the body on either side of the bladder.

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SUMMARY According to the present invention of surgical

instrument for passing a material into a body in a minimally invasive procedure comprises a first member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section, the arcuate section has at least two different radif of curvature. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

In certain preferred embodiments, the first member comprises a hollow outer tubular member. A stylet is at least partially movable within the outer tubular member and engageable with a material to pass the material within the body. The hollow outer tubular member and stylet enable the surgeon to remove the stylet from the outer tubular member and reinsert the stylet in the opposite position with respect to the outer tubular member. This structure also facilitates the placement of the material so that the material extends from a first side of the pelvis to a second side of the pelvis.

preferably A proximal portion of the arcuate section curves away from the longitudinal axis in a first direction

distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp. μ

In further aspect of the present invention, a surgical instrument for passing a material into a body in a minimally invasive procedure comprises a first member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section. The arcuate section be dimensioned and curved whereby when in use and in position in the body, the arcuate section extends from the skin over the obturator foramen, through the obturator foramen, to the vaginal wall. The shape of the first member facilitates the passing of the material into the body, in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments are described herein with reference to the drawings wherein:

- FIG. 1 is a side view of an instrument for use in a surgical procedure in accordance with an embodiment of the present invention;
- FIG. 2 is a side view of an outer member of the instrument in accordance with the embodiment of FIG. 1;
- FIG. 3 is a bottom view of the outer member of the instrument in accordance with the embodiment of FIGS. 1 and 2;
- FIG. 4 is a side view of a stylet of the instrument in accordance with the embodiment of FIGS. 1-3;
- FIG. 5 is a perspective view of a length of material used with the instrument in accordance with the embodiment of FIGS. 1-4,
- FIG. 6 is a sketch showing the relation of the vagina to the pelvis;
- FIG. 7 is a black and white photograph of the vaginal area during an initial stage of a surgical procedure in accordance with a further embodiment of the invention;

The outer tubular member desirably has a handle at a proximal end thereof. In certain preferred embodiments, the handle has a laterally extending portion. The arcuate section defines a first plane and the wing defines a second plane substantially perpendicular to the first plane.

The surgical instrument preferably includes a material and, in certain preferred embodiments, wherein the material comprises a generally flat tape. At least one end of the tape may be cut at an angle for ease of threading the tape into the stylet, in embodiments in which the stylet comprises a slot for receipt of the at least one end. The tape desirably comprises a material including multifilament strands, which may comprise polypropylene strands. The material may comprise a generally flat tape and the stylet may have a proximal end adapted to receive an end of the tape. The material may comprise an absorbable material.

The stylet is desirably positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member. In certain preferred embodiments, the stylet has a distal end that is blunt. The distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

In yet another aspect of the present invention, a surgical instrument for passing a material into a body comprises a tubular member having a longitudinal section defining a longitudinal axis and an arcuate section extending distally from the longitudinal section. Varcuate portion proximal portion which curves away longitudinal axis in a first direction and a distal portion which curves toward the longitudinal axis in a second direction. The shape of the first member facilitates the passing of the material into the body; in a minimally invasive procedure. The shape of the first member enables a material to be placed inside the body in a minimally invasive procedure so that the material extends through the obturator foramen.

A stylet is at least partially movable within the outer tubular member and engageable with a material to pass the material within the body. The hollow outer tubular

comprises a slot for receipt of the at least one end. The tape desirably comprises a material including multifilament strands, which may comprise polypropylene strands. The material may comprise a generally flat tape and the stylet may have a proximal end adapted to receive an end of the tape. The material may comprise an absorbable material.

The stylet is desirably positioned in the tubular member so that the proximal end of the stylet is located adjacent a proximal end of the tubular member. In certain preferred embodiments, the stylet has a distal end that is blunt. The distal end may comprise a blunt conical tip. In other embodiments, the stylet has a distal end that is sharp.

in a further aspect of the present invention method of suspending a portion of the urethra with a length of material comprises the steps of providing a surgical instrument having an outer tubular member including a longitudinal proximal end and a curved distal end and a stylet movable within the tubular member and configured to hold an end of the length of material. The method includes positioning the stylet within the tubular member. A vaginal incision and an incision located over the obturator foramen are made. The curved distal end of the surgical instrument is passed through the incision over the obturator foramen. The method includes manipulating the surgical instrument such that the curved distal end passes through the obturator foramen and out the vaginal incision. A proximal end of the stylet is engaged with a first end of the length of material, and the stylet is drawn through the tubular member to draw a portion of the length of material from the incision over the obturator foramen and through the vaginal incision.

The outer tubular member may be withdrawn through the incision over the obturator foramen leaving the length of material extending through the obturator foramen and out the vaginal incision. The step of passing the curved distal end of the surgical instrument through the incision over the obturator foramen desirably includes rotating the surgical instrument approximately 30 degrees upward in relation to the body. The surgical instrument is desirably elevated to position the curved distal end through the obturator foramen.

The surgical instrument is rotated to pass the curved distal end through the obturator foramen and out the vaginal incision.

method of suspending a portion of the urethra comprises the steps of passing a curved distal end of a surgical instrument through the body so that the instrument extends between a vaginal incision and a skin incision located over the obturator foramen. The surgical instrument has an outer tubular member including a longitudinal proximal end and a curved distal end and a stylet movable within the outer tubular member. The stylet is drawn through the body to draw the length of material through the body, extending between the vaginal incision and the incision over the obturator foramen.

The step of passing the curved distal end of the instrument desirably includes inserting the curved distal end of the instrument into the incision over the obturator foramen and moving the curved distal end through the obturator foramen, out the vaginal incision. The step of passing the curved distal end of the instrument desirably includes inserting the curved distal end into the vaginal incision. During the step of passing the curved distal end of the instrument, the stylet is desirably disposed within the outer tubular member.

The method may include, after the step of passing, withdrawing the stylet from the outer tubular member. The stylet may be reinserted in the outer tubular member so that an end of the stylet adapted to receive the material is disposed at the vaginal incision. The material is desirably disposed so that the material is received by the end of the stylet.

The step of drawing may include withdrawing the stylet through the outer tubular member, thereby drawing the material through the outer tubular member, and removing the outer tubular member through the body. The step of drawing may include withdrawing the stylet and outer tubular member from the body, thereby drawing the material through the body.